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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,052	03/22/2006	Giovanni Meazza	163-689	8978
7590 James V Costigan Hedman & Costigan 1185 Avenue of the Americas New York, NY 10036-2601			EXAMINER HAYLIN, ROBERT H	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 02/12/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/573,052

**Applicant(s)**

MEAZZA ET AL.

**Examiner**

ROBERT HAVLIN

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 3-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 13-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/8508)  
Paper No(s)/Mail Date 3/22/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

**Status of the claims:** Claims 1-16 are currently pending.

**Priority:** This application is a 371 of PCT/EP04/10653 (09/21/2004) and claims foreign priority to ITALY MI2003A 001855 (09/29/2003).

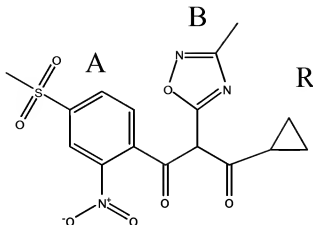
**IDS:** The IDS dated 3/22/2006 was considered.

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I (claims 1, 2, and 13-16; product of Formula I) in the reply filed on 12/3/2007 is acknowledged. The traversal is on the ground(s) that there is unity of invention. This is not found persuasive because the common technical feature linking the claims is a propyl-1,3-dione which are well known in the prior art and is disclosed in numerous references including the IDS document PL 171529. Therefore, the technical feature is not a contribution over the prior art and the claims are properly restricted.

The requirement is still deemed proper and is therefore made FINAL.

Applicant also elected the species of compound No. 22 (Table 1 on page 163; claims 1, 2, and 13-16 reading thereupon):



1-cyclopropyl-2-(3-methyl-1,2,4-oxadiazol-5-yl)-3-(4-(methylsulfonyl)-2-nitrophenyl)propane-1,3-dione

The examiner has searched the elected species; however as described in the following rejections no generic claim was found patentable. Therefore, the claims are restricted to the elected species and the remaining subject matter withdrawn.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 1, 2, and 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the definitions of the variables in the claims, it is not clear what the alternatives corresponding to the applicant's invention. For example, "R" and "A" as shown below does not clearly delineate which are the substituents and the substituted groups. There are numerous other examples in the claims where one of ordinary skill in the art would not be able to determine the metes and bounds of the claims based on the claim language and the specification, therefore

Art Unit: 1626

the claims are indefinite. The examiner attempted to get clarification on this matter by contacting James Costigan at 212-302-8989 on 2/7/2008, but the examiner was unsuccessful.

## A represents:

an aryl group optionally substituted by one or more substituents selected from halogen, NO<sub>2</sub>, CN, CHO, OH, linear or branched C<sub>1</sub>-C<sub>8</sub> alkyl, linear or branched C<sub>1</sub>-C<sub>8</sub> haloalkyl, linear or branched C<sub>1</sub>-C<sub>8</sub> alkoxy, linear or branched C<sub>1</sub>-C<sub>8</sub> haloalkoxy, C<sub>1</sub>-C<sub>8</sub> cyanoalkyl, C<sub>1</sub>-C<sub>8</sub> alkoxyalkyl, C<sub>1</sub>-C<sub>8</sub> alkylthioalkyl, C<sub>1</sub>-C<sub>8</sub> alkyldisulfidealkyl, C<sub>1</sub>-C<sub>8</sub> alkyldisulfonealkyl, C<sub>1</sub>-C<sub>8</sub> haloalkoxyalkyl, C<sub>1</sub>-C<sub>8</sub> haloalkylthioalkyl, C<sub>1</sub>-C<sub>8</sub> haloalkylsulfidealkyl, C<sub>1</sub>-C<sub>8</sub> haloalkylsulfonealkyl, C<sub>1</sub>-C<sub>8</sub> alkoxyalkoxy or C<sub>1</sub>-C<sub>8</sub> haloalkoxyalkoxy optionally substituted with a group selected from C<sub>1</sub>-C<sub>4</sub> alkoxy or C<sub>1</sub>-C<sub>4</sub> haloalkoxy, C<sub>1</sub>-C<sub>8</sub> alkylthioalkoxy, C<sub>1</sub>-C<sub>8</sub> haloalkylthioalkoxy, C<sub>1</sub>-C<sub>12</sub> dialkoxyalkyl, C<sub>1</sub>-C<sub>12</sub> dialkylthioalkyl, C<sub>1</sub>-C<sub>12</sub> dialkylthioalkoxy, C<sub>1</sub>-C<sub>12</sub> dialkoxyalkoxy, C<sub>1</sub>-C<sub>8</sub> haloalkoxyhaloalkoxy, C<sub>1</sub>-C<sub>10</sub> alkoxyalkoxyalkyl, C<sub>1</sub>-C<sub>8</sub> alkenyl, C<sub>1</sub>-C<sub>8</sub> haloalkenyl, C<sub>1</sub>-C<sub>8</sub> alkenyloxy, C<sub>1</sub>-C<sub>8</sub> haloalkenyloxy, C<sub>1</sub>-C<sub>8</sub> alkenyloxyalkoxy, C<sub>1</sub>-C<sub>8</sub> haloalkenyloxyalkoxy, C<sub>1</sub>-C<sub>8</sub> alkenyloxyalkoxy, C<sub>1</sub>-C<sub>8</sub> haloalkenyloxyalkoxy, C<sub>1</sub>-C<sub>12</sub> acylaminoalkoxy, C<sub>1</sub>-C<sub>8</sub> alkoxyiminoalkyl, C<sub>1</sub>-C<sub>8</sub> haloalkoxyiminoalkyl, C<sub>1</sub>-C<sub>8</sub> alkenyloxyiminoalkyl, C<sub>1</sub>-C<sub>8</sub> haloalkenyloxyiminoalkyl, C<sub>1</sub>-C<sub>8</sub> alkenyloxy-

R represents a hydrogen atom, a linear or branched C<sub>1</sub>-C<sub>8</sub> alkyl group, a linear or branched C<sub>1</sub>-C<sub>8</sub> haloalkyl group, a C<sub>3</sub>-C<sub>8</sub> cycloalkyl or C<sub>4</sub>-C<sub>12</sub> cyclo-alkylalkyl group optionally substituted with halogen atoms or C<sub>1</sub>-C<sub>8</sub> alkyl or C<sub>1</sub>-C<sub>8</sub> thioalkyl or C<sub>1</sub>-C<sub>8</sub> alkoxy or C<sub>1</sub>-C<sub>8</sub> alkoxy carbonyl groups, C<sub>2</sub>-C<sub>8</sub> alkenyl groups, C<sub>1</sub>-C<sub>8</sub> alkenyl groups, the latter two groups, in turn, optionally substituted with halogen atoms, a C<sub>3</sub>-C<sub>8</sub> cycloalkenyl group optionally substituted with halogen atoms or C<sub>1</sub>-C<sub>8</sub> alkyl groups, an aryl or arylalkyl group optionally substituted;

4. Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims use the term "active principle" which is not defined in the specification and would not convey clear meaning to one of ordinary skill in the art. Therefore, the claims are indefinite.
5. Claims 2, 13-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds of Formula I does not reasonably provide enablement for isomers of these compounds. The specification does not

Art Unit: 1626

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. The nature of the invention,
2. The state of the prior art,
3. The predictability or lack thereof in the art,
4. The amount of direction or guidance present,
5. The presence or absence of working examples,
6. The breadth of the claims,
7. The quantity of experimentation needed, and
8. The level of the skill in the art.

***The nature of the invention***

The nature of the invention is compounds of Formula I and isomers thereof.

***The state of the prior art and the predictability or lack thereof in the art***

The state of the prior art is that an isomer is any compound having the same composition, including constitutional isomers, which are compounds whose atoms are connected differently and stereoisomers. Constitutional isomers can contain different functional groups in varying positions.

***The amount of direction or guidance present and the presence or absence of working examples***

The only direction or guidance present in the instant specification is for the compounds of Formual I. There is no direction or guidance as to what type of isomers are included in the claims.

There is no data present in the instant specification for the preparation of any type of isomer, such as constitutional isomers.

Art Unit: 1626

***The breadth of the claims***

The instant breadth of the rejected claims is broader than the disclosure, specifically, the instant claims include any isomer, i.e. any compound with the same number of each atom.

***The quantity or experimentation needed and the level of skill in the art***

While the level of the skill in the pharmaceutical arts is high, it would require undue experimentation of one of ordinary skill in the art to prepare any isomer as instantly claimed since an isomer of the compounds need only have the same composition of atoms, not necessarily the same order of atoms and can have varying functional groups in varying positions. Therefore, the claims lack enablement for isomers.

This rejection can be overcome by deleting all instances of "and isomers".

***Conclusion***

No claim is in condition for allowance.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Havlin whose telephone number is (571) 272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/  
Examiner, Art Unit 1626

/Rebecca L Anderson/  
Primary Examiner, Art Unit 1626